

KNT/KW/16/6569

**B.Pharm Fifth Semester (C.B.S.) Examination**  
**REGULATORY AFFAIRS AND INTELLECTUAL PROPERTY RIGHT**  
**Paper—6 (5-T-6)**

Time : Three Hours]

[Maximum Marks : 80

**N.B. :—** (1) Q. No. 1 is compulsory.

(2) Attempt any **FOUR** questions from the remaining.

(3) Draw neat labeled diagram wherever necessary.

(4) Assume suitable data wherever necessary.

(5) Use of electronic calculator, excluding programmable calculator is permitted.

1. Solve any **FIVE** :—

- (a) Enlist various International Treaties and Conventions on IPR. Mention Global Drug Regulatory agencies.
- (b) Differentiate between — Generics and Biosimilars.
- (c) Give different types of Drug Master File (DMF).
- (d) Explain how Drug Regulatory Affairs department acts as a link between pharmaceutical industry and regulatory agency.
- (e) Give procedure of registering trade marks.
- (f) Write about role and responsibility of CDSCO. 5×4=20

- 2. (a) Give an account on Amendments to Indian Patent Act, 1970. 7
- (b) What do you mean by IND ? What are the contents and format of IND application ? 8
- 3. (a) What are the various stages of filing patent through PCT ? Mention advantages of PCT. 7
- (b) Define New Drug. Give an account on various stages in filing New Drug Application. 8
- 4. (a) Describe the role and responsibilities of Drug regulatory agency. 7
- (b) Give an account on Hatch—Waxmann Act, 1984. Describe various requirements for filing Abbreviated New Drug Application (ANDA). 8

5. (a) Define the terms :—
- (i) Patentability Criteria
  - (ii) Compulsory Licensing.
- Give the scope and special features of TRIPS agreement. 8
- (b) Give objectives and principles of Good Clinical Practice guideline (GCP). Add a note on Declaration of Helsinki. 7
6. (a) What do you mean by Common Technical Document (CTD) ? Give objectives and functions of ICH. 8
- (b) Give an account on Intellectual Property Laws in India. Add a note on copyright. 7
7. Write short notes on (any **THREE**) :—
- (a) Patent Infringement
  - (b) GATT and WTO
  - (c) Phases of Drug Development
  - (d) Good Manufacturing Practice guideline (GMP). 5×3=15